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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,036	08/08/2000	CHENGCAI CHU	PPD50288UST	2299

7590

11/06/2002

Hale and Dorr LLP
60 State Street
Boston, MA 02109

EXAMINER

KALLIS, RUSSELL

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 11/06/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

*proper response
is
Rule 116
amend after
final*

HF 07-95

Office Action Summary

Application No.

09/581,036

Applicant(s)

CHU ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7-14,16 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7-14,16 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The rejection of Claim 16 under 35 U.S.C. 101 is withdrawn in view of Applicant's amendments.

The rejection of Claims 1, 7-14, and 16 under 35 U.S.C. 112, second paragraph is withdrawn in view of Applicant's amendments.

Claim Rejections - 35 USC § 112

Claims 1, 7-14, and 16 remain rejected and newly added Claim 18 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of increasing the yield of a potato plant comprising transforming a potato plant with a DNA construct comprising the tuber specific patatin promoter operably linked to the alcR gene controlling the ethanol inducible alcA promoter operably linked to an invertase gene, does not reasonably provide enablement for a method of increasing the yield of any plant transformed with any DNA construct comprising one or more DNA sequences encoding a protein involved in sucrose sensing, transport, metabolism and/or uptake operably linked to any controllable promoter region controlled by an external chemical inducer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official actions mailed 4/09/02. Applicants arguments filed August 19, 2002 have been considered but are not deemed persuasive.

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Applicant asserts that the said invention, a method of increasing yield in a plant by transformation with a inducible promoter region, is fully enabled to the extent set forth in the claims because there is a reasonable correlation between the one exemplified plant species (i.e. potato transformed with the alcA promoter, alcR gene, and the potato patatin promoter) recited in the specification on page 18 lines 21-26, and the entire scope of the claimed invention, i.e. any plant comprising any inducible promoter regions induced by any chemical directed by any tissue or organ specific promoter (response pages 8-10).

Although the specification discloses other inducible systems in the specification, the specification does not provide guidance for methods of increasing yield in plants transformed with other inducible promoter systems. Given the lack of guidance in the specification with respect to other inducible expression systems undue trial and error experimentation would be required to practice the invention as claimed. Furthermore in the specification, on page 5 lines 26-31, Applicant admits that the effects of the "controlled" timing of expression of an invertase gene were "unexpected" suggesting that the genetic and chemical elements comprising the invention as broadly claimed requires far more than mere routine optimization.

Applicant further asserts that the Examiner may have misapprehended the Bussis and Sonnewald references (response page 9) in that although the rate of photosynthesis is decreased in plants transformed with invertase, the dry weight of the leaves of these transformed plants is higher than that of leaves from non-transformed plants. Thus the references do not teach a reduction in yield. Applicant asserts that the bridge between non-exemplified transformed plants and the exemplified transgenic potato is nothing more than routine optimization of Applicant's methods by one of skill in the art (response page 11).

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Applicants arguments are misguided because the reported yield measurements are in unit weight/unit leaf area (see Bussis, page 128, at bottom of page, Table 2) and do not compare the total leaf biomass or total biomass component in a leaf with the total area of equivalent wild type and transgenic leaves. Both the Sonnewald and Bussis references reported stunted growth in tobacco and potato plants overexpressing invertase respectively. Furthermore the ability to increase yield in any plant using any one of the different switch promoter systems encompassing different means of chemical induction for controlling the timing of gene expression is highly unpredictable. It is well known that not all plants respond to environmental stimuli in the same fashion. Further, CAM and C4 plants with Kranz anatomy have separated carbon metabolism temporally and spatially that would further confound any routine determination of optimal induction conditions for increasing yield.

Claim Rejections - 35 USC § 103

Claims 1, 7-14, and 16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Willmitzer *et al.* (U.S. Pat 5,436,394) in view of Caddick *et al.* (WO 93/21334). This rejection is maintained for the reasons of record set forth in the Official actions mailed 4/09/02. Applicants arguments filed August 19, 2002 have been considered but are not deemed persuasive.

Applicants assert that the combination of references does not provide sufficient motivation to render obvious the claimed invention. Applicant also asserts that Caddicks invention is more complex than that of the instant application such that one would not even have contemplated using it in conjunction with the invention of Willmitzer and hence the Applicant's

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claimed method of increasing yield by transforming an inducible promoter into a plant is inventive (response page 13).

Caddick provides motivation to use inducible promoters such as the alcA promoter in conjunction with the alcR gene under control of a promoter selected for a particular tissue to control gene expression both spatially and temporally to increase yield (see page 1, lines 15-27) and thus provides motivation to optimize the yield in potato transformed with invertase as taught by Willmitzer.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on Monday-Friday 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding, or if the examiner cannot be reached as indicated above, should be directed to the legal analyst, Sonya Williams, whose telephone number is (703) 308-0009.

Russell Kallis Ph.D.
November 4, 2002

A handwritten signature in black ink, appearing to read "Amy Nelson".

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600